



# Introduction

- **Brand name:** Talicia
- **Generic name:** Omeprazole, amoxicillin and rifabutin
- **Pharmacologic class:** Proton pump inhibitor + antibiotics (penicillin + rifamycin)
- **Strength and Formulation:**  
10mg/250mg/12.5mg; delayed-release capsules
- **Manufacturer:** RedHill Biopharma
- **How supplied:** Capsules—84, 168
- **Legal Classification:** Rx

# Talicia



# Indication

- For the treatment of ***Helicobacter pylori*** infection in adults

# Dosage and Administration

- Swallow whole
- Take with food
- $\geq 18$  yrs: 4 caps every 8hrs for 14 days
- Do not take with alcohol
- Hepatic or severe renal (GFR  $< 30$  mL/min) impairment: avoid

# Considerations for Special Populations

- **Pregnancy:** may cause fetal harm; not recommended
- **Nursing mothers:** amoxicillin present in human milk; may cause diarrhea in breast-fed infant
- **Females of reproductive potential:** rifabutin and amoxicillin can reduce effectiveness of hormonal contraceptives
- **Males of reproductive potential:** may impair fertility (based on animal studies)
- **Pediatric:** <18yrs: safety, effectiveness not established
- **Geriatrics:** studies did not include sufficient number of patients aged 65 and older to determine difference in response

# Considerations for Special Populations

- **Hepatic impairment:** avoid; exposure to omeprazole substantially increased
- **Renal impairment:** avoid in patients with severe impairment (GFR<30mL/min); amoxicillin primarily eliminated by the kidney

# Contraindications

- Hypersensitivity to the components of Talicia:
  - Amoxicillin or other  $\beta$ -lactam antibacterial drugs (eg, penicillins and cephalosporins)
  - Omeprazole or other benzimidazoles (eg, proton pump inhibitors and anthelmintics)
  - Rifabutin or any other rifamycins
- Omeprazole: concomitant rilpivirine-containing products
- Rifabutin: concomitant delavirdine, voriconazole



# Warnings/Precautions

- Discontinue and treat if hypersensitivity reactions occur
- Evaluate if diarrhea occurs
- Discontinue if acute interstitial nephritis develops
- Cutaneous and systemic lupus erythematosus
- Avoid in those with mononucleosis
- Uveitis: refer for an eye exam if suspected; suspend therapy if needed
- Hepatic or severe renal impairment (see Dosing)

# Interactions

- May be antagonized by other **CYP2C19** or **CYP3A4 inducers** (eg, St. John's wort, rifampin); avoid
- May antagonize **hormonal contraceptives**; use additional or alternative non-hormonal methods
- Omeprazole antagonizes **clopidogrel**; consider alternative anti-platelet therapy
- May be potentiated by **CYP2C19** and/or **CYP3A inhibitors** (eg, fluconazole, itraconazole, posaconazole, clarithromycin); avoid
- May potentiate **CYP2C19 substrates** (eg, citalopram, cilostazol, phenytoin, diazepam), high-dose methotrexate (avoid), digoxin, tacrolimus; monitor

# Interactions

- **Avoid** concomitant amprenavir, indinavir, lopinavir/ritonavir, saquinavir/ritonavir, ritonavir, tipranavir/ritonavir, fosamprenavir/ritonavir, nelfinavir
- Amoxicillin potentiated by **probenecid**
- Increased incidence of skin rash with allopurinol; discontinue allopurinol if occurs
- Monitor INR, PT with warfarin or other oral anticoagulants
- May alter absorption of **pH-dependent drugs** (eg, iron salts, erlotinib, dasatinib, nilotinib, mycophenolate mofetil, ketoconazole, itraconazole)

# Interactions

- Monitor drugs metabolized by CYP450 (eg, cyclosporine, disulfiram)
- May interfere with **neuroendocrine diagnostic tests**; discontinue Talicia 14 days prior to CgA level assessment; may need to repeat test
- Amoxicillin may cause false (+) glucose test with Benedict's soln
- May cause false (+) results with secretin stimulation test or urine tests for tetrahydrocannabinol

# Adverse Reactions

- **Most frequent** (incidence  $\geq 1\%$ ): diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, vulvovaginal candidiasis
- **Other**: possible *C.difficile*-associated diarrhea

# Mechanism of Action

- Talicia is a combination of antibacterial drugs (rifabutin, amoxicillin) and a proton pump inhibitor (omeprazole as omeprazole magnesium), an antisecretory drug
- Amoxicillin acts through the inhibition of cell wall biosynthesis that leads to the death of bacteria
- Rifabutin inhibits DNA-dependent RNA polymerase in susceptible microorganisms

# Clinical Trials

- Effectiveness and safety evaluated in a randomized, double-blind, controlled study in treatment-naïve *H. pylori*-positive adult patients complaining of epigastric pain/discomfort
- Patients were randomized 1:1 to Talicia or control (total daily dose of amoxicillin 3000mg and omeprazole 120mg) administered for 14 consecutive days

# Clinical Trials

- *H. pylori* eradication was confirmed with a negative  $^{13}\text{C}$  UBT or fecal antigen test performed  $\geq 28$  days post-therapy
- Negative test results were considered treatment successes
- Patients who tested positive were considered treatment failures
- Persistent indeterminate results and patients without any  $^{13}\text{C}$  UBT or fecal antigen test after baseline were considered as treatment failures



# Clinical Trials

## **Eradication Rates of *H. pylori*:**

- Success: 83.8% with Talicia (n=228) vs 57.7% with control (n=227)
- Difference in response rates: 26.1% (95% CI, 18.0-34.1);  $P < .0001$

# Clinical Trials

- Randomized, double-blind, placebo-controlled study was performed and provided supportive evidence for the efficacy of Talicia
- 77 patients taking Talicia and 41 patients taking placebo were included in the ITT population
- Eradication rate of 76.6% (95% CI, 66.0-84.7) for the Talicia-treated patients compared with 2.4% for placebo-treated patients
- Eleven patients in the Talicia arm and 4 patients in placebo arm were classified as treatment failures due to missing  $^{13}\text{C}$  UBT results at the test-of-cure visit

# New Product Monograph

- For more information view the product monograph available at:

<https://www.empr.com/drug/talicia/>